OPENING STATEMENT OF
REP. EDWARD J. MARKEY (D-MA)
COMMERCE COMMITTEE HEARING ON THE
IMPLEMENTATION OF THE FDA MODERNIZATION ACT OF 1997

October 7, 1998

Mr. Chairman, let me begin by commending you and Mr. Dingell for your stewardship of this Committee during the 105th Congress. I applaud your leadership and your willingness to reach across the aisle on so many issues to reach consensus.

I would also like to take this opportunity to welcome my constituents, Albert Jean and his father, Gary, who have come down from Reading, Massachusetts to share their remarkable story with us this afternoon. The Jean family has reaped the benefits of our legislative effort last year, and I want to thank Albert for his courageous testimony – his informative presentation is a tribute to his family and to his community.

Mr. Chairman, just over a year ago, the Committee engaged in a vigorous discussion on the merits of the FDA Modernization Act of 1997. We attempted as a Committee and as a Congress to strike the delicate balance between maintaining the strength of the Food and Drug Administration's protective function for public health, while at the same time enhancing the agency's ability to efficiently process new drug and device applications. The United States continues to have the safest food and drugs in the world because American consumers and patients demand that the FDA be given full authority to reign in the renegades and require that food, drug, and device manufacturers maintain the highest possible safety and effectiveness standards before allowing products to come to market. I want to applaud the FDA for the steps it has taken to perform that balancing act and to meet nearly every single deadline established in the Modernization Act.

While many of the reforms we passed were necessary and appropriate, re-authorizing the Prescription Drug User Fee Act for example, I made it a point during last year's mark-up to express my reservations about the potential dangers of the "Off-label" promotion provisions contained in the bill. I said then, and I repeat now, that allowing companies to market a product for unsupported uses could seriously imperil thousands of consumers.

I remain troubled by the potential off-label abuses that may arise out of this provision of the FDA Modernization Act. And I am disturbed that almost all of the industry representatives testifying today have listed as among their most serious concerns with the implementation of the Act, the FDA's reluctance to give them carte-blanche in promoting and advertising off-label uses for their drugs and devices.

Two newspaper articles that appeared just last week which highlighted the potential problems presented by off-label promotion.

On September 27, in *The Washington Post*, reporter Robert O'Harrow, Jr. described the horror and anger felt by a doctor who was visited by a Pharmacy Benefit Management company pharmacist who quote, "opened a file containing medical information about a number of his patients and began making suggestions about how to treat them." An Alexandria pharmacist claimed to be contacted repeatedly by these Pharmacy Benefit Managers or PBMs about individual patients. According to the *Post* story, PBMs were also

making suggestions about changing prescription drugs to those manufactured by the PBMs parent company – a large pharmaceutical interest. One of the PBMs spokesmen was quoted in the story as saying that quote "Our clinical specialists are intended to serve as an informational resource to physicians by providing scientifically supported information and recommendations about quality, cost-effective pharmaceutical care."

According to the *Post*, the top three pharmacy benefit managers are owned by Merck & Co., Eli Lilly & Co., and SmithKline Beecham. These relationships create glaring conflicts-of-interest with respect to off-label promotion of drug uses. The situation is inflamed by the privacy implications of the PBMs aggressive marketing tactics chronicled in the *Post*.

Perhaps more troubling, on September 30, the *Wall Street Journal* ran a story titled, "How a Drug Approved By the FDA Turned Into a Lethal Failure." This story follows the problematic history of the FDAs decision to approve the drug Duract, a decision reached over the objection of a top FDA medical adviser, and after the intense and sustained lobbying of the manufacturer, Wyeth-Ayerst Laboratories. The company advertised the drug in medical journals as an alternative to addictive painkillers. While cautious language about Duract was buried deep in the fine print of its label, company sales reps reportedly disseminated erroneous information about the dangers of prolonged use of the drug. As a result, doctors over-prescribed Duract for conditions such as osteoarthritis – a condition the drug's label said that it was not meant to treat. The consequences of this off-label indication for Duract were deadly. After four deaths and eight liver transplants, the drug was finally removed from circulation on June 22. It's worth noting that the Fen-Phen tragedy was also the result of an off-label use for this combination of drugs.

It is important to get life-saving drugs and devices to needy patients in a timely fashion, but we mustn't lose sight of the fact that the FDA must be vigilant in role as protector of the health and safety of American consumers. I am hopeful that the proposed rules for dissemination of information on off-label uses keeps the this most important of FDA obligations in mind – protecting public health.

Mr. Chairman, thank you for calling this hearing. I look forward to exploring these issues with today's witnesses during the course of our discussion this afternoon.